

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-1430V

UNPUBLISHED

SANDRA ANZALONE,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 7, 2022

Special Processing Unit (SPU);
Findings of Fact; Site of Vaccination
Influenza (Flu) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

Joseph J. Manna, Lipsitz, Green, et al., Buffalo, NY, for Petitioner.

Jennifer A. Shah, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On October 22, 2020, Sandra Anzalone filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”), a defined Table injury, after receiving an influenza (“flu”) vaccine on October 25, 2017. Petition at 1, ¶ 2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the flu vaccine was most likely administered in Petitioner's left deltoid, as alleged.

I. Relevant Procedural History

Along with the Petition, Ms. Anzalone filed her affidavit and the medical records usually required under the Vaccine Act. Exhibits 1-11, ECF No. 1; see Section 11 (c). The case was activated and assigned to SPU on February 26, 2021. ECF No. 8.

During the initial status conference, held on April 22, 2021, Respondent's counsel indicated that Respondent would like to review any medical records related to an earlier left shoulder injury in 2006. Order, issued Apr. 23, 2021, at 1, ECF No. 11. She asked if there was a related worker's compensation claim for either the 2006 or current 2017 injury. In response, Petitioner's counsel indicated that Petitioner was informed that her current injury did not qualify for worker's compensation, that she believed Petitioner had not needed treatment for her 2006 injury, that she would confirm that fact and ask about a worker's compensation claim related to the earlier injury, and that Petitioner would file any additional medical records obtained. *Id.* The parties then discussed the lack of documentation regarding the site of vaccination and the potential need for a fact ruling from me on the issue. *Id.* at 2.

Three months later, Petitioner filed additional outstanding medical records from 2015 to the present related to treatment she received from specialists such as her cardiologist. Exhibits 12-17, filed July 22, 2021, ECF No. 14. Petitioner did not file any medical records related to her 2006 injury. However, she filed a statement of completion indicating that all medical records had been filed. ECF No. 15.

On September 21, 2021, Respondent filed a status report noting that Petitioner had not filed medical records related to her 2006 injury, worker's compensation records related to her current injury, or further documentation regarding the site of vaccination. Status Report at 1, ECF No. 17. Respondent further indicated that he assumed those records did not exist (*id.* at 2 n.1) and believed that the factual issue regarding site of vaccination "should be resolved through further record development while the DICP review is pending" (*id.* at 2).

On November 19, 2021, Petitioner filed a detailed affidavit, additional medical records, and documentation regarding her 2006 back and shoulder injury, the site of her 2017 vaccination, and the denial of her worker's compensation claim for the 2017 injury. Exhibits 18-20, ECF No. 19. She also filed a status report providing detailed information regarding medical records related to her 2006 injury which may still be outstanding and

her efforts to obtain those records. ECF No. 20. On January 6, 2022, she filed a brief regarding the site of vaccination. ECF No. 22.

In response to an inquiry from court personnel, Respondent's counsel indicated that Respondent wished to file a responsive brief. However, on January 28, 2022, Respondent instead filed a status report indicating that "[a]t this time, [he] takes no position on the site of administration of the subject vaccination in this case . . . [but] reserves the right to amend his response once the medical review" is complete. ECF No. 23.

Respondent was informed on several occasions that I wished to address any factual issues not requiring medical expertise prior to the HHS review. Additionally, all available documentation related to Petitioner's October 25, 2017 vaccination has been filed. The issue is now ripe for adjudication.

II. Issue

At issue is whether Petitioner received the October 25, 2017 flu vaccine in her left deltoid, as alleged.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25,

1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery v. Sec’y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make the finding regarding site of vaccination after a complete review of the record to include all medical records, affidavits, documentation, briefing, and additional evidence filed. Specifically, I base the finding on the following evidence:

- The vaccine record filed by Petitioner, consisting of the one-page insurance consent form, shows she was administered a full dose of the flu vaccine on October 25, 2017. Exhibit 2 at 1. The section indicating site of injection is blank – no option is checked. *Id.*
- The vaccine record contains the signature of the nurse administering the vaccine. Exhibit 2 at 1. In her affidavit, Petitioner indicated she received the vaccine at her place of employment - the Ford Motor Company in Buffalo, New York. Exhibit 6 at ¶ 2. Employment records indicate these vaccinations were provided by a separate agency visiting the plant. Exhibit 19 at 3 (indicating Petitioner “tried contacting the agency that gave her the injection to report the incident”).
- Petitioner’s employment records show when she returned to work the next day, Petitioner visited the occupational nurse on duty, complaining of left arm pain due to the flu shot she received the previous day. Exhibit 19 at 3. She reported that the shot did not hurt when administered but that she was unable to raise her left arm by 10pm that evening. *Id.*
- The nurse who treated Petitioner observed ecchymosis³ at the injection site, but no redness or swelling. Exhibit 19 at 3. Characterizing the site’s location as atypical, she indicated it was “at the top of left arm shoulder.” *Id.* She observed limited range of motion (“ROM”) in Petitioner’s left arm/shoulder. *Id.*
- At the October 26 visit, as well as a follow-up visit on November 7, the occupational health nurse instructed Petitioner to apply heat and follow-up with her primary care provider (“PCP”). Exhibit 19 at 4. She assessed Petitioner as “Fit for Work” on November 7, 2017. *Id.* at 4.

³ Ecchymosis is “a small hemorrhagic spot, larger than a petechia, in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY at 588 (32th ed. 2012).

- On November 7, 2017, Petitioner also visited her PCP for left arm pain, characterized as a reaction to the flu vaccine. Exhibit 3 at 23-24. At this visit, she provided the same medical history - left shoulder pain and limited ROM which started in the evening after she received a flu vaccine administered too high in her left deltoid. *Id.* at 23. Petitioner's PCP observed pin with palpitation and prescribed x-rays and an MRI. *Id.* at 23-24.
- In the record from x-rays, performed on November 9, 2017, it was noted that Petitioner had a history of pain in her "left deltoid area over the shoulder after getting [a] flu shot 2 weeks ago." Exhibit 3 at 25.
- In the report from the MRI, performed on November 27, 2017, it was reported that Petitioner had a shot on October 25, 2017, and now has pain and decreased ROM in the left shoulder. Exhibit 3 at 26. The MRI revealed "[r]ather severe subacromial/subdeltoid bursitis, . . . some internal debris, . . . [t]iny partial undersurface tear distally in the supraspinatus tendon, [a] [s]mall interstitial tear also seen in the infraspinatus tendon, [and] [n]o full-thickness tear noted." *Id.*
- On November 29, 2017, Petitioner returned to her PCP for a follow-up of her "left shoulder pain after influenza vaccine from work." Exhibit 3 at 29. Again, observing pain upon palpitation and limited ROM, the PCP discussed the MRI results, diagnosed Petitioner with subacromial bursitis of the left shoulder joint, and referred her to an orthopedist. *Id.* at 29-30.
- When seen by the orthopedist on December 1, 2017, Petitioner again reported left shoulder pain which began on October 25, 2017, after she received a flu shot at work. Exhibit 8 at 11. She rated her pain, "located around her deltoid muscle," as seven out of ten. The orthopedist observed "[m]ild tenderness over the left superior and lateral aspect of the shoulder without significant swelling, erythema, or warmth" and limited ROM. *Id.* He administered a cortisone injection. *Id.* at 12.
- Also, on December 1, 2017, Petitioner submitted a worker's compensation claim. Exhibit 20 at 11-12. On the claim form, she described her injury as continued pain after getting a flu shot which occurred on October 25, 2017, and was witnessed by the nurse from Health Maxim who administered the vaccination. *Id.*

- A left shoulder ultrasound, performed on December 3, 2017, revealed an “increased subacromial bursitis fluid suggestive of bursitis with [the] suggestion of internal debris without increased blood flow.” Exhibit 8 at 16. It appears an ultrasound guided cortisone injection was administered at this appointment. *Id.* at 16-17 (handout regarding cortisone injections and reference to earlier injection at the next orthopedic appointment on December 8, 2017).
- Petitioner repeated the same medical history when seen by her orthopedist on December 8 and 15, 2017, June 19, August 24, and October 5, 2018. Exhibit 8 at 17, 23, 34, 40, 46. On December 8, 2017, it was noted that Petitioner was currently not working. She received another ultrasound cortisone injection at that visit. *Id.* at 21. At the next orthopedic appointment on December 15, Petitioner was cleared to return to work without restriction on December 22, 2017.
- On April 1, 2019, Petitioner sought a second opinion from another orthopedist. Exhibit 9 at 6-8. She again attributed her left shoulder pain to the flu vaccine she received in October 2017, indicating that her pain and limited ROM began the next day. *Id.* at 7.
- Petitioner began physical therapy (“PT”) on June 19, 2019. Exhibit 11 at 2-4. Throughout her PT records, there are multiple entries linking Petitioner’s left shoulder pain with the flu vaccine she received. *Id.* at 2, 11, 19, 34, 49, 52, 64, 67, 79, 86, 88, 92, 95, 107, 110.

The above medical entries show that, when seeking treatment for her left shoulder pain, Petitioner consistently attributed her pain to the vaccine she reported receiving in her left arm. She provided these histories to the occupational nurse at work, her PCP, two orthopedists, and her physical therapist within a day of vaccination and throughout the subsequent two years thereafter. While originating from Petitioner, these statements are set forth in contemporaneous records, and should therefore be afforded greater weight than any subsequent assertion or witness statement. The Federal Circuit has stated that “[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions.” *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this class of information, even when the record in question simply memorializes what the petitioner said at the time.

Additionally, in both medical records and her affidavit, Petitioner described the flu vaccine as improperly administered – given too high in her left deltoid. Exhibit 3 at 23; Exhibit 6 at ¶ 2. The occupational health nurse who treated Petitioner the day after vaccination agreed. Exhibit 19 at 3. She observed bruising at the site of vaccination – identified as the top of Petitioner’s *left* arm/shoulder. *Id.* This entry showing the nurse observed physical evidence supporting Petitioner’s contention that the vaccine was administered in her left deltoid is extremely probative.

Although the vaccine record does not indicate the exact site of vaccination, it clearly establishes that, on October 25, 2017, Petitioner received a flu vaccine. Furthermore, the medical histories provided by Petitioner in the contemporaneously created medical records and supporting evidence of the occupational health nurse’s observations provide persuasive evidence showing the vaccine was administered in Petitioner’s left deltoid. And there is a dearth of evidence that the vaccine was administered in any other location. I thus determine, based on the entire record, that Petitioner has provided preponderant evidence establishing that the flu vaccine to which Petitioner attributes her SIRVA was most likely administered in her left deltoid on October 25, 2017.

V. Scheduling Order

Based on recent data, I expect the HHS review to be completed in this case in March 2022. Although not clear whether Petitioner’s injury meets all criteria for a Table SIRVA, given my finding of fact regarding the site of vaccination, it is appropriate for Petitioner to forward a demand and supporting documentation to Respondent prior to the HHS review. And I previously instructed Petitioner to begin finalizing a demand and to gather any supporting documentation needed. Order at 2, Apr. 23, 2021, ECF No. 11. Petitioner should continue to finalize her demand which she may forward to Respondent, along with her supporting documentation, at any time.

Respondent shall file a status report indicating how he intends to proceed by no later than Wednesday, March 23, 2022.

Petitioner shall file a status report updating me on her demand by no later than Wednesday, March 23, 2022. The status report shall indicate the date by which Petitioner provided, or intends to provide, a demand and supporting documentation to Respondent. Additionally, Petitioner shall confirm whether any Medicaid lien exists, and if so, indicate the date by which Petitioner anticipates providing Respondent a letter from the appropriate state agency verifying the amount of the lien.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master